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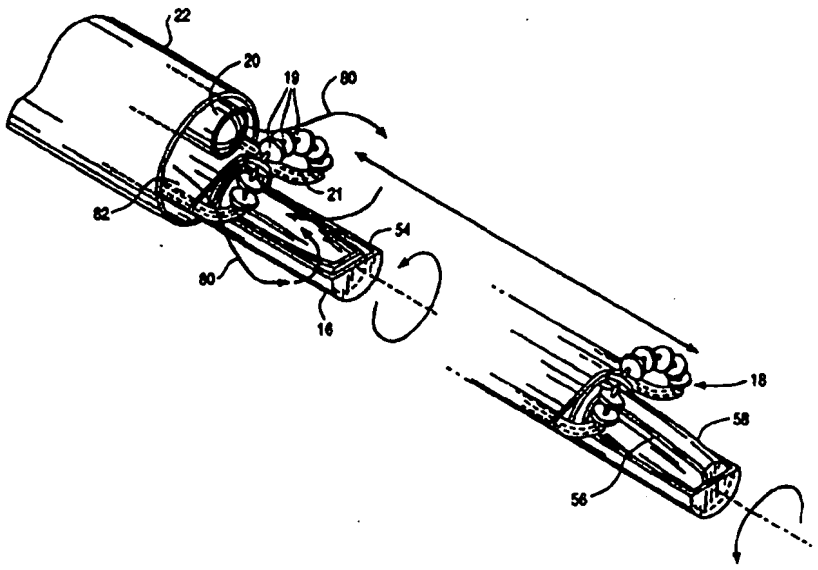

(57) Abstract

The present invention provides an electrosurgical device comprising a shaft (22) having a proximal end and a distal end. A wire (21) is disposed near the distal end of the shaft, the wire (21) defining a transverse curve and being energizable. A plurality of rolling elements (19) are rotatably disposed over the wire (21) and remove target tissue when the wire is energized. The curved wire (21) fans the rolling elements (19) out, increasing the active contact area of the electrosurgical device with the target tissue, and also directing energy into the tissue along discrete separated paths.

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ELECTROSURGICAL DEVICE HAVING ROLLERS FOR ABLATING AND SEGMENTING OF TISSUES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Continuation-in-part of U.S. Patent Application Serial No. 08/705,229, filed August 29, 1996, (Attorney Docket No. 16944-001210), which was a Continuation-In-Part of U.S. Provisional Patent Application Serial No. 60/008,226, (initially U.S. Serial No. 08/555,553; Attorney Docket No. 16944-001200), filed November 8, 1995, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to a method and device for electrosurgical tissue ablation, and in particular, provides an electrosurgical device with rolling elements which promote detachment of extractable tissue fragments.

Electrocautery has been in use for many years as a general surgical tool, such as for transcervical fibroid removal. In an exemplary fibroid removal process, the uterus is first flooded (typically with a nonconductive fluid, such as sorbitol-mannitol fluid or the like) under sufficient pressure to separate the walls of the uterus and render the surgical site suitable for optical fiber observation. This procedure is generally described as uterine cavity distension. During this flooding, an electrocautery surgical tool is inserted into the uterus through the cervix. Electrical current at high voltage settings (typically an alternating current about 750 KHz and 2000-9000 volts) is transmitted from a cutting surface of the surgical instrument to the surgical site. The cutting surface typically consists of a wire or solid shape. The transmission of current to the uterus is monopolar, and the circuit is completed by a conductive path

to the power unit through a conductive pad applied to the patient's skin.

The electrical current is concentrated at the cutting surface. Heat generated from the resistance of tissue to the flow of electrical current is high enough to vaporize cells near the cutting surface. Thus, a cut is made with very little physical resistance to the cutting motion. Heat from the cut cauterizes small blood vessels so that visibility and control remain good.

During uterine cavity distension, a similar electrical resistance heating may be used at lower power settings to cauterize bleeding tissue and to kill selected areas of the tissue through ablation. Such cautery electrodes can be larger in area so as to treat broader surfaces. Cautery is used in gynecology to ablate the endometrial lining of the uterus. This procedure is often performed using a conductive roller which heats a wide swath of tissue along the inner surface of the uterus.

An exemplary electrosurgical tissue resection device and method to sever strips of tissue, and to morcellate and aspirate the severed tissue, were described in co-pending U.S. Patent Application Serial No. 08/322,680, the full disclosure of which is incorporated herein by reference. That device includes both a rotating chopping mechanism and an electrosurgical cutting wire. The electrosurgical cutting wire is particularly well-suited for removal of strips of tissue from the uterus, prostate, or other internal body cavities. The rotating chopping mechanism severs these strips of removed tissue into tissue fragments, the electrosurgical cutting wire and rotating chopping mechanisms being independently optimized for these two distinct cutting operations. U.S. Provisional Patent Application Serial No. 60/006,325, the full disclosure of which is also incorporated herein by reference, describes the use of a probe having a similar cutting wire and tissue chopping mechanism, in combination with a removable ablation/ coagulation roller. This roller facilitates the ablation of proximally oriented fibroid tissues of the uterus, and may also allow simultaneous

cutting and coagulation of those blood vessels which remain open after the tissue strips have been severed.

Although the exemplary resection methods and devices described above are highly effective, work in connection with the present invention has shown that they could benefit from still further refinements. For example, the cutting wire is capable of cutting larger strips of tissue than can be easily accommodated by the chopping mechanism. Although the cutting wire shape may be easily modified to increase the amount of tissue removed, the large strip of severed tissue would reduce the rate at which the strip enters the morcellator aperture. This limits the speed at which tissue can be removed from the uterus or other internal surgical site, thus prolonging, and also increasing the cost, of the tissue resection procedure.

Recently, it has been proposed to utilize electrosurgical surfaces, together with high power (200-300 watts), to remove large volumes of tissue. This approach generally relies on sheer electrosurgical power to vaporize the target tissue. While this proposed process may allow removal of the vaporized tissue with an irrigation stream, it relies on an inefficient use of high electrical power levels within internal surgical sites, and may therefore impose a significant risk to the surrounding tissues. Additionally, such vaporization will release tissue debris and/or large tissue fragments which can clog an aspiration flow path, and thereby interrupt the tissue removal process.

For the above reasons, it would be desirable to provide improved electrosurgical devices and methods for the removal of internal tissues. It would be particularly desirable to provide an electrosurgical cutting member which would both detach tissue and break-up the tissue into extractable tissue fragments. It would further be advantageous if such an improved electrosurgical cutting member could utilize power more efficiently than the brute vaporization of tissues. Ideally, this improved cutting member should be compatible with tissue removal systems and methods already under development, but would allow an increased volume of tissue to be removed.

SUMMARY OF THE INVENTION

In a first aspect, the present invention provides an electrosurgical device comprising a shaft having a proximal end and a distal end. A wire is disposed near the distal end of the shaft, the wire defining a curve and being energizable with electrical potential. A plurality of rolling elements are rotatably disposed over the wire along the curve to fragment and remove tissue when the wire is energized and a plurality of the rolling elements roll against the tissue. Advantageously, the curved wire fans the rolling elements out, increasing the active contact area of the electrosurgical device with the target tissue, and also directing energy into the tissue along discretely separated paths. The electrosurgical energy from the rolling elements can remove tissue as discrete, more easily aspirated tissue fragments, without resorting to brute vaporization of substantially the entire target tissue. Therefore, the wire and rollers provide an electrosurgical cutting member having a large projected area to remove a large total volume of tissue with each pass, but which does not produce a correspondingly large (and difficult to aspirate) strip of tissue.

In another aspect, the present invention provides an electrosurgical device for removing target tissue from a surgical site within an internal body cavity. The device comprises a shaft having a proximal end, a distal end, and an aspiration lumen between the aperture and the proximal end. An energizable wire is transversely mounted near the aperture of the shaft, and a spurred rolling element is rotatably disposed on the wire. As used herein, "spurred" means a rolling element having a cross-section with a plurality of discrete protruding elements dispersed about the axis of rotation. These protruding elements concentrate electrical potential at discrete radial positions, fragmenting and removing tissue when the wire is energized and the rolling element is rolled against the tissue. Additionally, the spurs will provide deeper penetration of the ablation or coagulation power, and will also generate better traction to promote uniform rolling.

In another aspect, the present invention provides a method for electrosurgically removing tissue, the method comprising introducing a probe into an internal body cavity. An axial end of the probe is manipulated to roll at least one rolling element over a target tissue within the internal body cavity, while the rolling element is energized with sufficient electrical energy to detach the target tissue from the internal body cavity, at least a portion of the target tissue forming tissue fragments. These tissue fragments are then aspirated through an aspiration lumen of the probe. Advantageously, separation and fragmentation of a large amount of the target tissue may be accomplished with lower electrosurgical energy than is required to vaporize substantially all of the target tissue, and with little likelihood of clogging a morcellator or other aspiration system.

In yet another aspect, the present invention provides an electrosurgical device comprising a shaft having distal and proximal ends and wire mounted near the distal end of the shaft. A plurality of rolling elements are disposed along the wire. Each rolling element is rotatable about the wire and has at least one edge which is oriented radially outward relative to the wire. This edge will concentrate and direct electrosurgical potential into tissues which are in rolling contact with at least some of the rolling elements.

In a final aspect, the present invention provides a method for fabricating an electrosurgical device, the method comprising passing a wire through a plurality of rolling elements so that each rolling element has at least one edge which is radially oriented outward relative to the wire. The wire is mounted near a distal end of a shaft so that the edges of the rolling elements are rotatable when the shaft is manipulated from the proximal end. The rolling elements are electrically coupled to the proximal end of the shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a resection probe according to the principles of the present invention, showing a proximal handle and several of the probe system connections.

Fig. 2 illustrates a resection probe system, including the probe of Fig. 1.

Fig. 3 illustrates a method of use of the probe of Fig. 1 for transcervical fibroid removal from the uterus.

Figs. 4 and 5 illustrate the axial cutting motion of the cutting member and morcellator, and also show the transverse arched wire supporting and fanning-out the rolling elements of the cutting member at the distal end of the probe of Fig. 1.

Figs. 6A and 6B illustrate a disk-shaped rolling element for use in the cutting member of the probe of Fig. 1.

Figs. 7-7B illustrate alternative rolling elements having a spurred cross-section for use in the cutting member of the probe of Fig. 1.

Fig. 8 is a perspective view of an exemplary spurred rolling element for use in the cutting member of the probe of Fig. 1.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring now to Fig. 1, resection probe 10 generally has a proximal end 12 and a distal end 14. A probe shaft 16 supports a cutting member 18 near its distal end, the cutting member here including a plurality of rolling elements 19. Fiber-optic imaging scope 20 is distally oriented toward cutting member 18, and runs proximally within sheath 22.

A probe handle housing 24 includes an actuation handle 26 for axially translating the shaft and cutting member relative to the sheath. An irrigation fluid port 28 and aspiration port 30 provide a continuous flow path for a clear, non-conductive fluid such as sorbitol-mannitol, mannitol, glycine, or the like. Aspiration flow is controlled by an aspiration valve 32, so that the distension pressure may be maintained independently from flow. Electrosurgical connector wires 34 and a flex drive input 36 provide external electrical

and mechanical power, minimizing the weight of housing 24. An optical image eyepiece 38 is removably attached to housing 24 to optically direct the resection procedure. Optionally, an ultrasound transceiver may be mounted on the distal end of the probe, as is more fully explained in U.S. Patent Application Serial No. 08/322,680. Such a distal ultrasound transducer may optionally comprise a one- or two-dimensional phased array to allow scanning of the resection tissue independent of any mechanical movement of the transducer probe.

Referring now to Fig. 2, a resection system 40 utilizes the input and output connectors on the housing of probe 10, together with standard stand-alone surgical system components, to minimize cost, weight, and fatigue when using probe 10 in a resection procedure. An irrigation supply 41 is connected to irrigation port 28 to provide a continuous flow of irrigation fluid during resection. Preferably, irrigation supply 41 comprises a standard irrigation supply bag suspended above the surgical site to provide a constant pressure gravity feed, allowing distension pressure to be varied simply by changing the height of the irrigation supply. Alternatively, a valve or controlled flow pump may be used to supply irrigation fluid.

In the exemplary embodiment, aspiration, mechanical rotation, and electrosurgical potential are coupled to the shaft through a disposable cartridge 25 on shaft housing 24, the disposable cartridge reciprocating with the shaft as shown. This disposable cartridge structure facilitates replacement of the cutting wire/shaft assembly (including the inner and outer tubes of the chopping mechanism or "morcellator") which would otherwise limit probe life. Fluid which leaves aspiration port 30 is directed through a filter canister 42 and then to an aspiration sump 44. Filter 42 removes the solid tissue fragments from the aspiration fluid for analysis. Sump 44 is preferably connected to a standard vacuum supply line to promote the withdrawal of aspiration fluid through the probe. Aspiration vacuum control is conveniently provided by aspiration valve 32 (see Fig. 1).

Mechanical power is supplied to flex drive input 36 by drive motor 48. Drive motor 48 preferably rotates at least in the range between 500 and 1500 rpm, and typically allows for rotation in either direction, or oscillating rotation back and forth. The morcellator generally shears tissue mechanically, without requiring electrosurgical potential. The morcellator is a preferred feature, to promote aspiration of larger tissue fragments without clogging, but may not be required where tissue fragment size is limited by the shape of the rolling element of the cutting member, the electrosurgical power supplied, the relative motion of the rolling elements against the target tissue, and the like.

Controlled electrosurgical power is supplied through electrosurgical wires 34 to the cutting member by power unit 46. As is more fully described in co-pending Application Serial No. 60/006,325, previously incorporated by reference, a switch (not shown) optionally allows application of electrosurgical power to be directed to a roller mounted distally of the aperture (not shown). The irrigation and aspiration flow paths, together with the optical viewing scope, are more fully described in co-pending U.S. Patent Application Serial No. 08/542,289, the full disclosure of which is herein incorporated by reference.

Referring to Fig. 3, an exemplary method for using resection probe 10 typically comprises transcervically introducing sheath 22 into the uterus U. Such insertion is facilitated by use of an obturator. Manipulation of the probe is facilitated by limiting the sheath to a maximum of about 27 Fr (about 9 mm in diameter). Once the sheath is properly positioned, the obturator is removed and the shaft 16, cutting member 18, and the scope 20 are inserted through the shaft and proximal housing 24 is attached to sheath coupling 50.

The probe is manipulated from the proximal housing 24 using articulation handle 26. The surgeon inserts the fingers of one hand through finger handle 70, and inserts the thumb of the same hand through thumb ring 72. Preferably, the fingers are held stationary while the thumb ring extends the shaft and cutting member distally from the sheath. Thumb ring

72 is biased toward the proximal direction, so that removal of strips of tissue typically takes place under the assistance of biasing spring 73.

Removal of fibroid tissue from the uterus U begins with the cutting member 18 extended distally from the sheath 22 and energized with RF power, as described above. As illustrated in Fig. 3, the shaft is generally aligned with the tissue to be removed so that proximally actuating thumb ring 72 draws cutting member 18 through fibroid and/or endometrial tissue. The procedure is directed using scope 20, preferably while the scope and sheath are held substantially motionless using finger handle 70. Performing each cut towards the viewing scope helps to avoid inadvertently perforating uterus U.

In an alternative embodiment of the method of the present invention, the surgeon may manipulate the thumb ring relative to the finger handle to bring the cutting member 18 to a preferred viewing distance from scope 20, and then translate the shaft and housing assemblies together proximally. This provides a longer cutting stroke for cutting member 18, and decreases the time required for the resection procedure.

As cutting member 18 moves proximally, rolling elements 19 generally roll against the fibroid or endometrial tissue. These rolling elements fan outward radially, so that multiple separate fibroid tissue segments are detached from the uterus by each stroke of the cutting member. Therefore, the detached tissue segments are each smaller than an equivalent single strip of severed tissue, and are significantly easier to draw into the morcellator for extraction. The cutting member can thus have an increased axial projection area, i.e., can remove a greater volume of tissue with each stroke, without overwhelming the morcellator. Those of skill in the art will appreciate that such methods and devices will have many advantageous applications, including for the removal of selected thoracic tissues, particularly lung tissue, tissues of the bladder, and tissues of the prostate.

Referring now to Figs. 4 and 5, the orientation and flow of aspiration flow path 80 over scope 20 is illustrated. The interaction of shaving port 56 on chopping tube 58 with aperture 54 of shaft 16 is also clearly seen. In the exemplary embodiment, cutting member 18 includes an energized wire 21 having proximal ends disposed within and electrically insulated from support insulated tubes 81 which are soldered to shaft 16, the tubes and shaft being insulated with shrink-wrap tubing 82. As shown most clearly in the simplified end view of Fig. 5, wire 21 forms a transverse arch along which the rolling elements 19 are disposed. Insulation 83 between wire 21 and tubes 81 is also shown. Preferably, the entire cutting member 18, including wire 21 and rolling elements 19 are smaller than the lumen of sheath 22 to facilitate insertion and removal of the cutting member/shaft assembly.

Referring now to Figs. 6A and B, rolling element 19 optionally comprises a simple disk with a central passage for the wire. The rolling element generally comprises an electrically conductive material which will withstand the temperatures created in the ablation process, preferably comprising brass, stainless steel, plated steel, or plated stainless steel.

Referring to Figs. 7-7B, a plurality of spurred rolling elements 92 optionally directly replace the plurality of disks in cutting member 18 (see Figs. 4 and 5). Each spurred rolling element includes a plurality of radially protruding elements 94 to further fragment the fibroid tissue, and a plurality of these spurred rolling elements may be fanned outward along a curved wire, as described above. Alternatively, a single spurred cylinder 96 supported on a straight, transverse energized wire could span the ablation area as a single roller to produce a square cut. In a still further alternative, a spurred sphere 98 mounted on a similar straight energized wire will create an arched cut.

Referring now to Fig. 8, an exemplary spurred rolling element 100 will be typically include between 4 and 10 radially protruding elements 94, ideally having about 6. The spurred rollers will generally be between about 0.050 inches

and 0.125 inches in diameter (to the ends of protruding elements 94), with an axial thickness of between about 0.005 inches and 0.09 inches. In the exemplary embodiment of the roller, the surfaces between adjacent protruding elements define an angle α of roughly 45°. Preferably, there will be between about 6 and 50 such rollers along the wire of the cutting element.

The ends 102 of protruding elements 94 will ideally slope radially outward toward the axial center, as shown. While the preferred slope of ends will be up to about 20°, it should be understood that the actual shape of the rollers may vary somewhat from the theoretical shape shown. In fact, the rollers will often be fabricated by masking sheets of metal and chemically etching the material surrounding the desired roller shape, generally producing somewhat rounder edges than that shown at the end surface 102 of protruding element 94. The rollers will generally be formed from stainless steel, but may alternatively comprise titanium, tungsten, or the like.

Although the foregoing invention has been described in detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modification may be practiced in the scope of the appended claims.

WHAT IS CLAIMED IS:

1. An electrosurgical device comprising:

a shaft having a proximal end and a distal end;

an energizable wire disposed near the distal end of the shaft, the wire defining a curve; and

a plurality of rolling elements rotatably disposed over the wire along the curve to fragment and remove target tissue when the wire is energized and a plurality of the rolling elements roll against the target tissue.

2. An electrosurgical device as claimed in claim 1, wherein the rolling elements comprise disks.

3. An electrosurgical device as claimed in claim 1, wherein the rolling elements comprise spurs.

4. An electrosurgical device as claimed in claim 1, wherein the curve comprises an arch which is transverse to the shaft so that the rolling elements fan outward and roll against the target tissue as the shaft is reciprocated.

5. An electrosurgical device as claimed in claim 4, wherein the shaft includes an aperture near the distal end and a lumen between the aperture and the proximal end.

6. An electrosurgical device as claimed in claim 5, further comprising a morcellator disposed within the lumen of the shaft to reduce the size of tissue fragments passing through the lumen.

7. An electrosurgical device as claimed in claim 6, further comprising a sheath having an infusion lumen disposed along the shaft, the infusion lumen having a fluid outlet proximally of the rolling elements, and an imaging mechanism disposed adjacent to the fluid outlet and oriented distally toward the rolling elements.

8. An electrosurgical device for removing target tissue from a surgical site within an internal body cavity, the electrosurgical device comprising:

a shaft having a proximal end, a distal end, a fluid infusion lumen, an aperture near the distal end, and an aspiration lumen between the aperture and the proximal end;

an energizable wire transversely mounted near the aperture of the shaft; and

a spurred rolling element rotatably disposed on the wire to fragment and remove tissue when the wire is energized and the rolling element rolls axially against the target tissue.

9. An electrosurgical device as claimed in claim 8, wherein the rolling element comprises a spurred cylinder.

10. An electrosurgical device as claimed in claim 8, wherein the rolling element comprises a spurred sphere.

11. An electrosurgical device as claimed in claim 8, wherein the wire defines a curve, and wherein a plurality of spurs are rotatably disposed over the wire along the curve.

12. An electrosurgical device as claimed in claim 8, further comprising a morcellator disposed within the lumen of the shaft to reduce the size of tissue fragments passing through the lumen.

13. An electrosurgical device as claimed in claim 8, wherein the infusion lumen has a fluid outlet proximally of the rolling element, and further comprising an imaging mechanism disposed adjacent to the fluid outlet and oriented distally toward the rolling element.

14. A method for electrosurgically removing tissue from a surgical site within an internal body cavity, the method comprising:

introducing a distal end of a probe into the internal body cavity;

manipulating a proximal end of the probe to roll at least one rolling element over a target tissue within the internal body cavity;

energizing the at least one rolling element of the probe with sufficient electrical energy to detach the target tissue from the surgical site, at least a portion of the detached target tissue forming tissue fragments; and

aspirating the tissue fragments through an aspiration lumen of the probe.

15. A method as claimed in claim 14, further comprising fanning a plurality of rotating elements outward by supporting the rotating elements along a curve of a wire.

16. A method as claimed in claim 14, wherein rolling the at least one rolling element comprises rolling a spurred rolling element against the tissue.

17. A method as claimed in claim 14, wherein the energizing step comprises supplying less electrical potential than is required to vaporize substantially all of the target tissue.

18. A method as claimed in claim 14, wherein the probe is introduced transcervically into the uterus, and wherein the target tissue comprises a member selected from the group containing fibroid tissues, endometrial tissues, tissues of the lung, tissues of the bladder, and tissues of the prostate.

19. An electrosurgical device comprising:

a shaft having a proximal end and a distal end;

a wire mounted near the distal end of the shaft; and

a plurality of rolling elements disposed along the wire, each rolling element being rotatable about the wire and having at least one edge which is oriented radially outward

relative to the wire so as to concentrate and direct electrosurgical potential into tissues in rolling contact with at least some of the rolling elements.

20. A method for fabricating an electrosurgical device comprising:

passing a wire through a plurality of rolling elements so that each rolling element has at least one edge which is radially oriented outward relative to the wire;

mounting the wire near a distal end of a probe so that the edges of the rolling elements are rotatable against tissues when the shaft is manipulated from the proximal end; and

electrically coupling the rolling elements to the proximal end of the shaft.

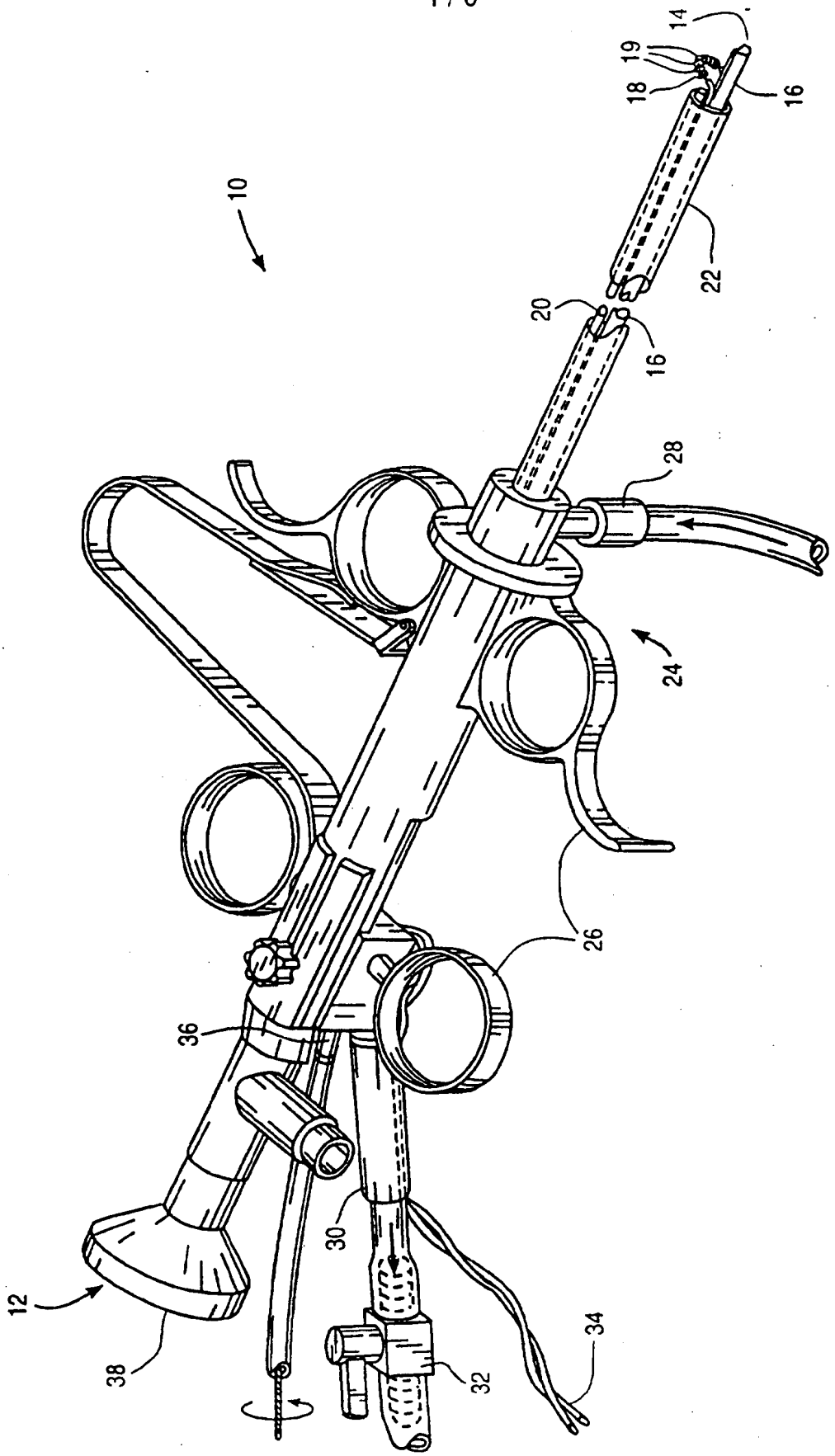

FIG. 1

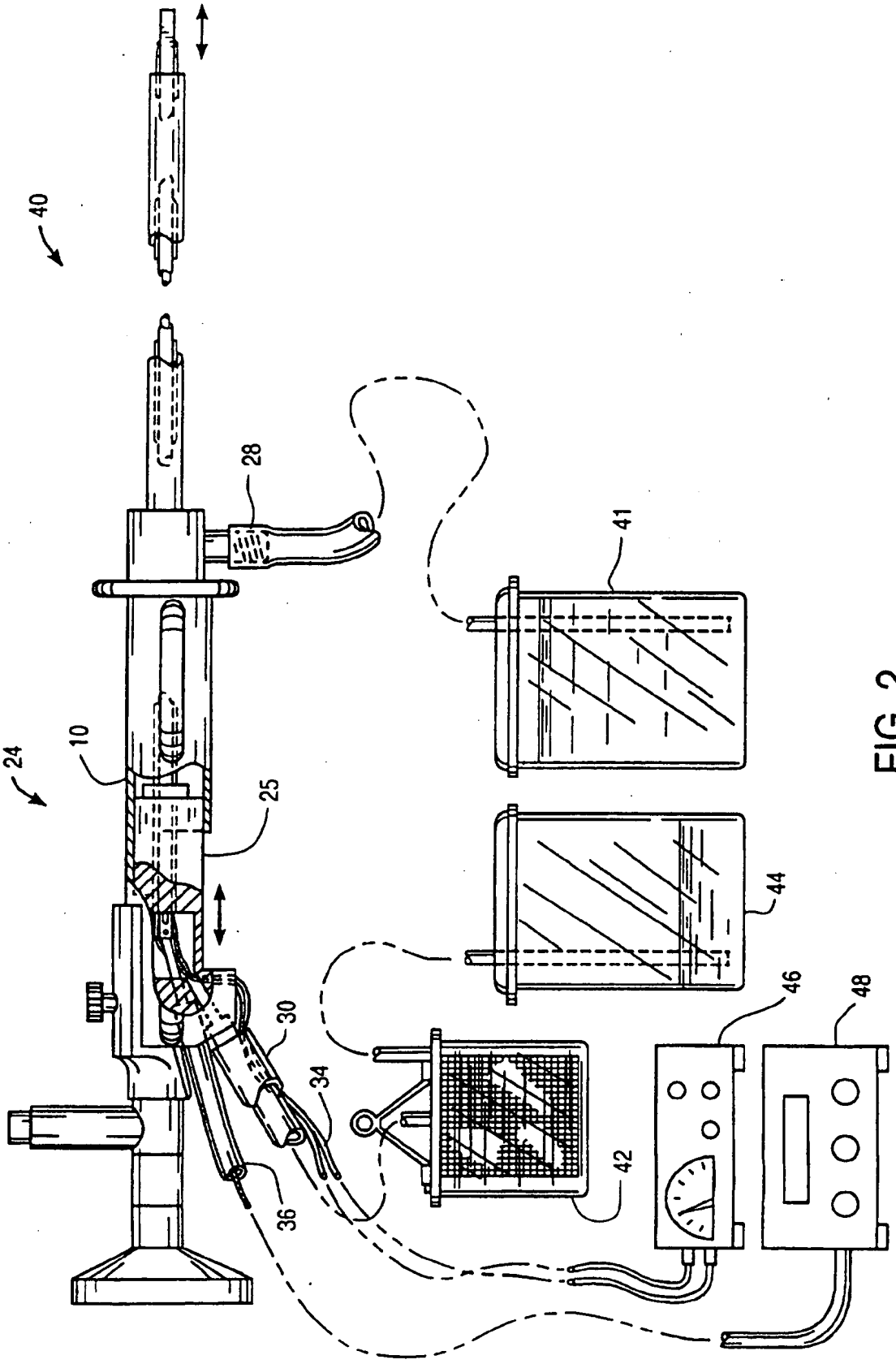

FIG. 2

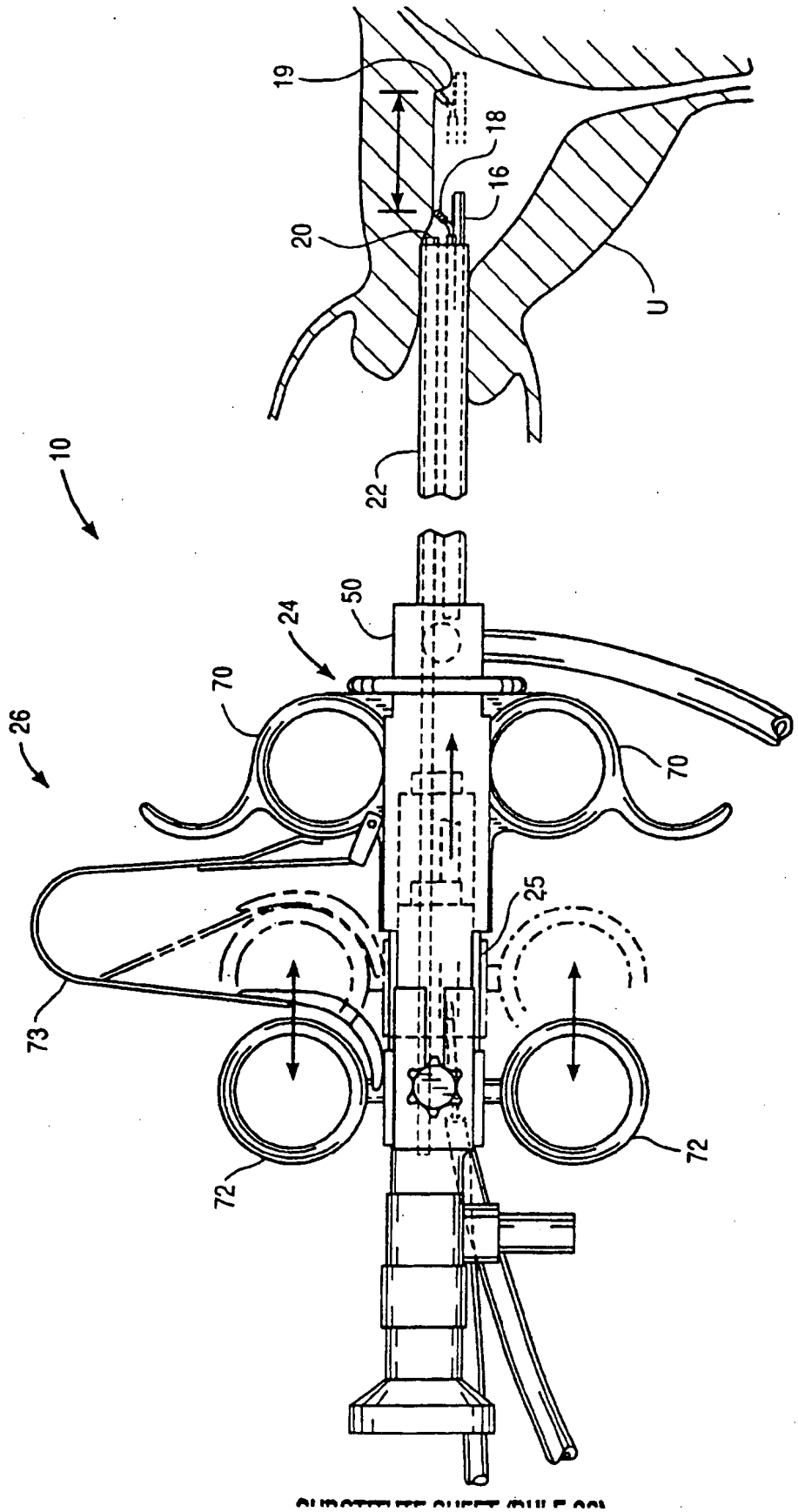

FIG. 3

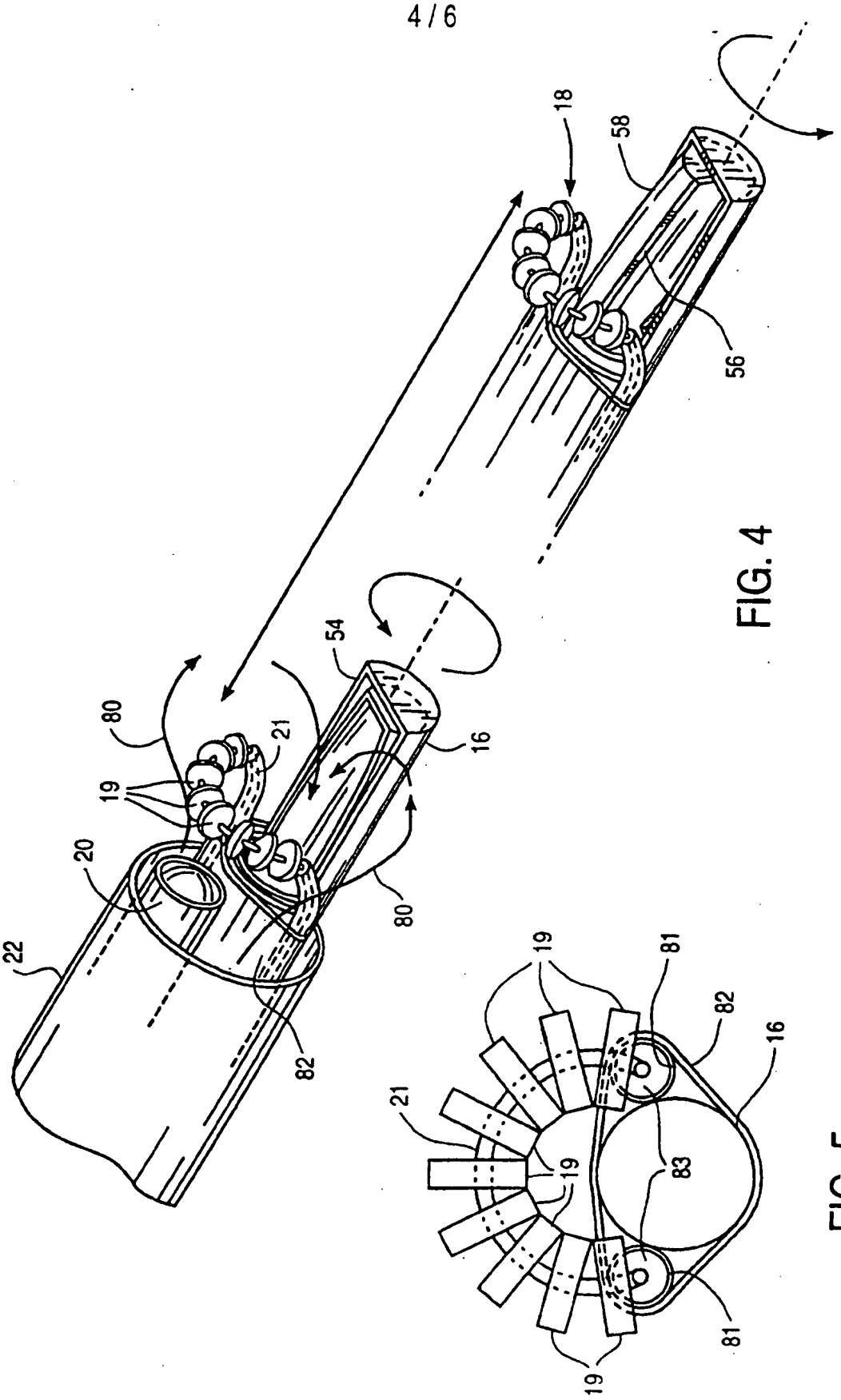

FIG. 4

FIG. 5

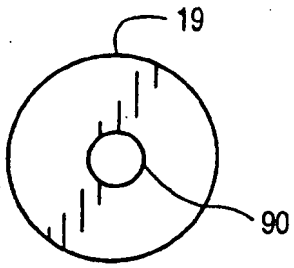

FIG. 6B

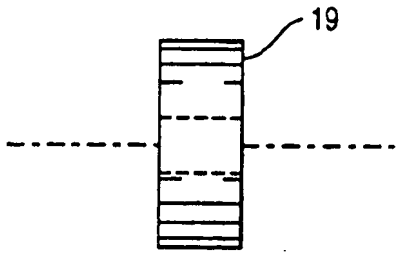

FIG. 6A

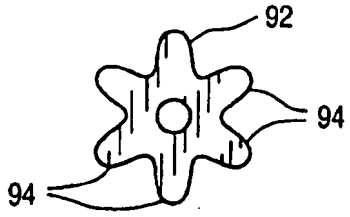

FIG. 7

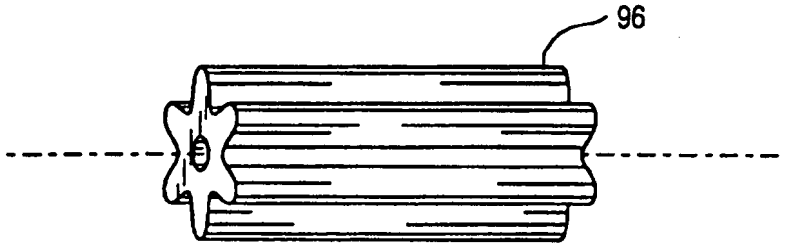

FIG. 7A

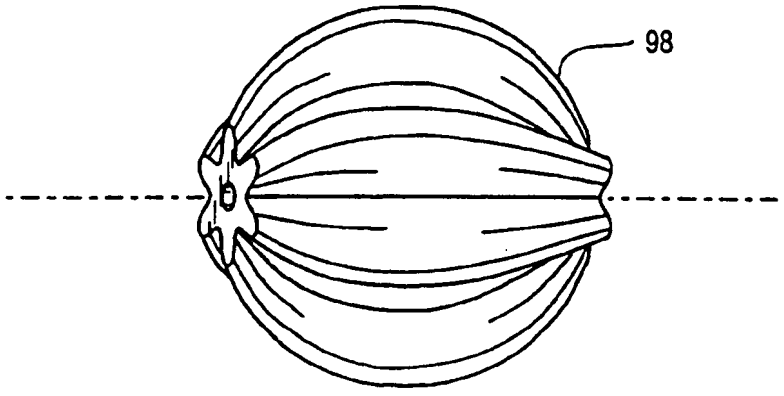

FIG. 7B

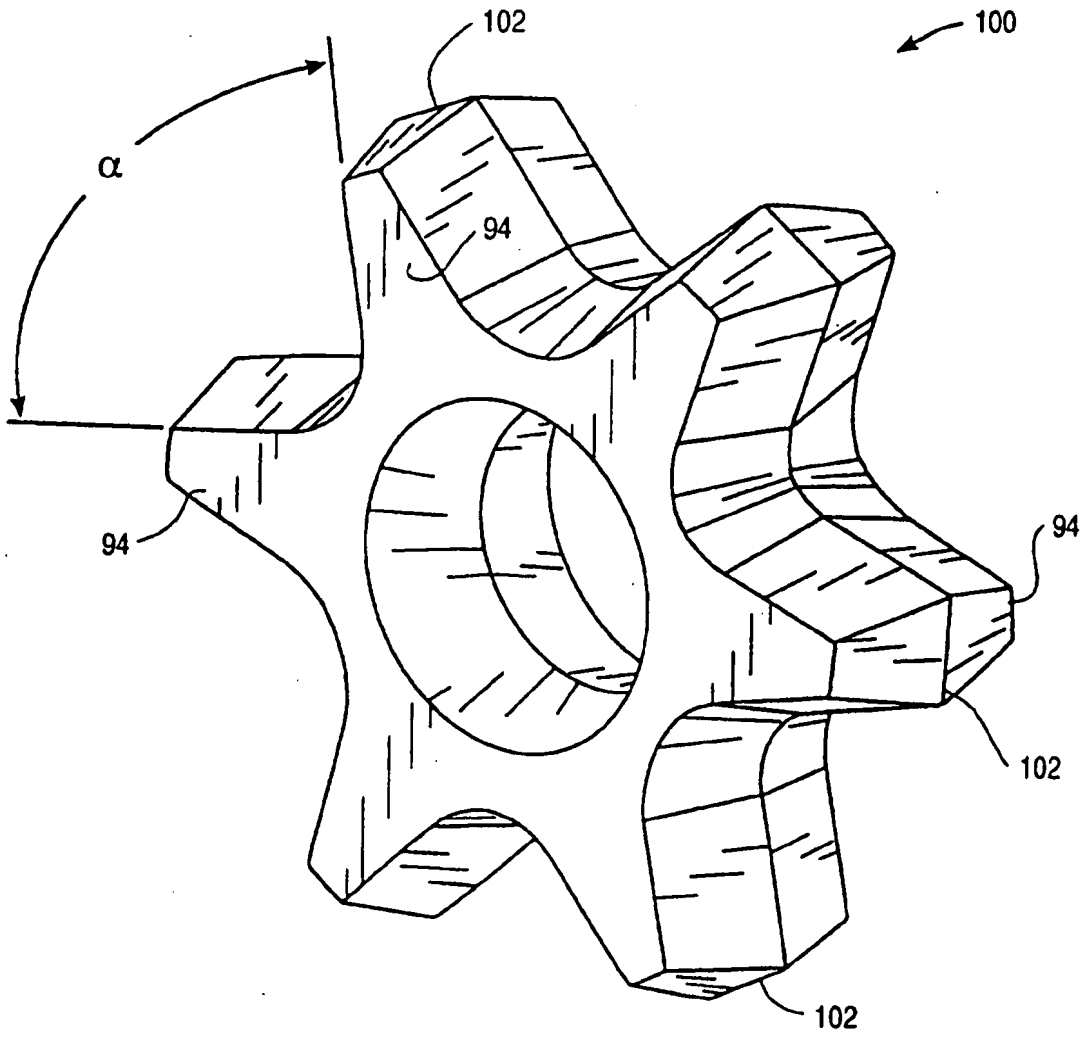

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/17454

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/39
US CL :606/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/104, 105, 160; 604/22; 606/41, 42, 45-50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,354,296 A (TURKEL) 11 October 1994, Fig. 6, whole document.	20 --- 1-19
Y	US 4,955,882 A (HAKKY) 11 September 1990, Fig. 2b, and whole document.	6, 7, 12
Y,P	US 5,549,605 A (HAHNEN) 27 August 1996, whole document.	3, 8-13, 16
Y	US 4,726,370 A (KARASAWA et al) 23 February 1988, whole document.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 JANUARY 1997	21 FEB 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer Diane Smith for MICHAEL PEFFLEY Telephone No. (703) 308-4305